Summary and Overview

Safety, Efficacy and Microbiological Considerations

System 83 Plus™ Washer-Disinfector

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Notes

1. Intended Use, General Information: The System 83 Plus™ *Washer-Disinfector* (also referred to as the "*System 83 Plus"*) is intended for washing *and* high-level disinfecting one or two submersible flexible endoscopes that do not contact normally sterile areas of the body and that feature several internal channels. The types of flexible endoscopes for which the *System 83 Plus* is labeled include those that are used to examine, diagnose and treat diseases of the gastrointestinal (GI) tract and pulmonary tract—for example, colonoscopes and bronchoscopes.

The *System 83 Plus* has been shown using a patented simulated in-use "multi-site" decontamination protocol (U.S. Patent No. 6,428,746) under worst-case conditions to clean—namely, achieve at least a 3 log reduction of soil—and to high-level disinfect—namely, achieve at least a 6 log reduction of resistant mycobacteria—a multi-channeled flexible endoscope and its removable components, including its valves. Because the *System 83 Plus* both cleans *and* high-level disinfects the endoscope using a standardized process, the summation of these two log reductions is expected after completion of a full cycle. (*Note***:** A 3 log reduction of bioburden means that the process reduced the initial amount of bioburden by 99.9%.)

Moreover, the *System 83 Plus* uses an external water filtration assembly that typically includes a 5 micron sediment *pre*-filter and 0.1 micron bacterial *post*-filter, to produce "bacteria-free" rinse water. (This assembly may also include a 25 micron pre-filter, depending on the quality of the facility's water.)

To date, there are no reports of an endoscope reprocessed by the *System 83 Plus* transmitting a microorganism or virus, such as the hepatitis C virus, when the *System 83 Plus*, as well as the detergent and the liquid chemical sterilant/disinfectant (LCS), are used in accordance with their respective labeling and published reprocessing guidelines and recommendations. The safety of the *System 83 Plus* is well-established, and several million endoscopes have been reprocessed by it without incident.

The *System 83 Plus* features the *same* standardized process as the *System 83 Plus* MiniFlex *Washer-Disinfector* (refer to the "Summary and Overview" booklet for the *MiniFlex* at: www.myendosite.com/fdabooklet_2.pdf), both of which are intended to supplement and augment manual pre-cleaning and endoscope drying as instructed by published endoscope-reprocessing guidelines and the instructions provided by the endoscope's manufacturer.

The System 83 Plus *Washer-Disinfector* is designed to:

- be used in accordance with the reprocessing instructions described in the operator's manual of the endoscope;
- satisfy the label requirements (e.g., time, temperature, and number of required terminal water rinses) of all LCSs labeled for reprocessing flexible endoscopes (refer to: *http:// www.fda.gov/cdrh/ode/germlab.html*);
- meet or exceed the reprocessing standards established by the ASGE, SGNA, the CDC and other endoscope-reprocessing and infection-control organizations (visit SGNA's website, *www.sgna.org,* for a set of step-by-step reprocessing instructions); and
- standardize the reprocessing protocol—namely, cleaning, chemical immersion, and water rinsing—to improve patient safety, minimize staff exposure to the LCS and its vapors, and minimize variability inherent to manual reprocessing.

Because arguably it is the most challenging endoscope to reprocess, a side-viewing ERCP duodenoscope was used during pre-market simulated in-use testing. Demonstration that the *System 83 Plus* can effectively clean and high-level disinfect a duodenoscope reasonably indicates that virtually all types of endoscopes less complex in design (e.g., endoscopes with a fewer number of channels; endoscopes with wider and shorter channels that are less restrictive to flow, such as a bronchoscope) can also be successfully reprocessed using the *System 83 Plus*, provided all of the endoscope's potentially contaminated surfaces are accounted for, adapted to, and in contact with the detergent, high-level disinfectant, and rinse water. (Refer to this booklet's section entitled *"An important paradigm for testing of endoscopes"* on page 18.)

2. Overview and Features:

An unique, simulated in-use *per site* protocol was used to evaluate the effectiveness of the System 83 Plus *Washer-Disinfector*. This protocol (U.S. Patent No. 6,428,746), which was also used to evaluate the *MiniFlex* washer-disinfector (refer to the *MiniFlex's* "Summary and Overview" booklet), uses positive control and test endoscopes to compare the number of microorganisms on *each* of the endoscope's many surfaces *before* and *after* reprocessing as required to evaluate the effectiveness of the *System 83 Plus*. In general, the greater the log reduction, the more effective the decontamination process. (For more details, refer to the "*Positive control, test instruments"* on page 8.)

Most other simulated in-use protocols used to evaluate the effectiveness of a decontamination process for reusable medical instruments are based on standards published by the *American Society for Testing and Materials* (ASTM) for *cleaning* (ASTM: Designation E 2314-03), *disinfection* (ASTM: Designation E 1837-96) and *sterilization* (ASTM: Designation E 1766-95) processes. Each of these ASTM protocols are lacking, however, and, instead of yielding a log reduction per *site*, as required to ensure patient safety and as required by the patented protocol used to evaluate the effectiveness of the *System 83 Plus*, each of these ASTM's standards yields instead a log reduction per *instrument*—a methodology that is prone to "false-negative" results.

The *System 83 Plus* features an automated and standardized process that has been validated during clinical and simulated in-use testing. When used in accordance with its labeling and the labeling of the detergent, liquid chemical sterilant/disinfectant, and endoscope, the *System 83 Plus* washes, high-level disinfects, and rinses with water one or two submersible endoscopes.

3 *Failure to use the System 83 Plus in accordance with it labeling, much of which is discussed in this document, can result in ineffective reprocessing and adverse consequences.*

The System 83 Plus *Washer-Disinfector* features:

[A] an automated **ultrasonic wash phase** that washes the endoscope, removes fine organic debris, and reduces the number of microorganisms on the endoscope prior to high-level disinfection. During the wash phase: (**1**) the endoscope is completely immersed in several gallons of fresh, filtered water mixed with a detergent, such as Tergal 800, which Custom Ultrasonics markets; (**2**) the endoscope is exposed to ultrasonic energy; and (**3**) a re-circulating pump irrigates each of the endoscope's channels and the biopsy port with detergent.

➲ Detergents other than Tergal 800 may be used provided they are: **(a)** specifically formulated for ultrasonic cleaning, **(b)** compatible with the components of the endoscope *and* the *System 83 Plus*, and **(c)** for which validated simulated in-use data (e.g., microbiological or equivalent) demonstrate the detergent's effectiveness when used to clean endoscopes during *worst-case* testing conditions. (Note that the temperature of the detergent solution is determined by the water temperature, which for Tergal 800 is required to be 110 ± 5^{o} F.)

3 Like reusable biopsy forceps, flexible endoscopes are complex instruments that typically contain at least one difficult-to-clean internal channel. To achieve thorough cleaning, published reprocessing guidelines instruct users first to clean biopsy forceps manually using a brush and detergent solution, followed by ultrasonic cleaning, the effectiveness of which has been clearly established. According to these published guidelines, manual cleaning alone is insufficient. The use of ultrasonic energy to clean flexible endoscopes is based on this same conclusion and is recommended to remove fine patient debris that remains on the instrument after manual cleaning, thereby improving and enhancing the effectiveness of the cleaning process.

▶ *The System 83 Plus is designed to elevate the standard of care and to establish for heat-sensitive flexible endoscopes the same standard established for biopsy forceps.*

[B] an automated **high-level disinfection phase** that destroys microorganisms remaining on the endoscope after cleaning. During this phase: **(1)** the endoscope is completely immersed in several gallons of a user-selected liquid chemical sterilant/disinfectant (LCS) labeled for the high-level disinfection of endoscopes (see: *http://www.fda.gov/cdrh/ode/germlab.html*); and **(2)** a re-circulating pump irrigates each of the endoscope's channels and the biopsy port with the LCS. The immersion time and temperature of the LCS is determined by its labeling and the medical literature. The *System 83 Plus* features a heater and temperature control to elevate and monitor the temperature of the LCS as may be required by the LCS's labeling. No ultrasonic energy is produced during this phase.

[C] an automated **water rinse phase** that follows both the wash and high-level disinfection phases. This phase removes potentially toxic chemical residues from the endoscope's surfaces. The endoscope is rinsed once with fresh, filtered "bacteria-free" water after the wash phase and three (or two) times after the high-level disinfection. As stated above, the *System 83 Plus's* water rinse phase uses tap water that has been filtered by an external water filtration assembly, which typically includes a 5 micron sediment pre-filter and a 0.1 micron bacterial post-filter. (The assembly may also include a 25 micron pre-filter, depending on the quality of the facility's water.)

The labeling of most LCSs requires that high-level disinfection be followed by three separate water rinses. Two separate water rinses instead of three may be sufficient, provided: **(a)** published data demonstrate that two separate water rinses are sufficient to remove all detectable levels of the LCS from the endoscope (i.e., a third water rinse provides no additional benefit to the patient, compared to two water rinses); and **(b)** these data have been reviewed by the FDA for safety and effectiveness.

REPROCESSING PHASE	TIME (minutes)	Fluid volumes:† Manual (milliliters)	Fluid volumes: The System 83 Plus (liters)
Wash	3.0	0 - ? (variable)	**4.5**
Rinse (water)	1.5	0 - ? (variable)	**2.3**
High-level disinfection	To be specified	—	**Depends on time**
ı **An example:**	20.0	0 - ? (variable)	**30.0**
First Rinse	1.0	0 - ? (variable)	**1.5**
Second Rinse (optional)	1.0	0 - ? (variable)	**1.5**
Final Rinse	1.5	0 - ? (variable)	**2.3**

Table 1: *Cycle parameters for the* System 83 Plus Washer-Disinfector.

During each water rinse phase: **(1)** the endoscope is completely immersed in several gallons of fresh, bacteria-free (filtered) rinse water; **(2)** the endoscope is exposed to ultrasonic energy; and **(3)** a re-circulating pump irrigates each of the endoscope's channels and the biopsy port with fresh, bacteria-free (filtered) rinse water.

As previously described, the endoscope is exposed to ultrasonic energy during every reprocessing phase except the chemical immersion phase. Also, at the end of each phase, the endoscope's channels are each automatically purged with compressed air, to remove residual fluid.

3. Description:

The System 83 Plus *Washer-Disinfector*:

- ☑ is an automated endoscope reprocessor (AER) - specifically, a washer-disinfector—labeled for terminal **cleaning** and **high-level disinfection** of flexible endoscopes;
- ☑ can reprocess one or two endoscopes at a time;
- ☑ was validated using a patented, simulated in-use decontamination protocol under *worst-case* conditions (U.S. Patent No. 6,428,746);
- ☑ irrigates *each* of the endoscope's channels during each reprocessing phase. The *System 83 Plus* provides one channel-tubing adapter for each endoscope channel. In contrast, other

† When manually reprocessing an endoscope, the volumes of the detergent, the liquid chemical sterilant/disinfectant, and the rinse water are variable, dependent on personnel technique, and can vary significantly from, for example, zero, if the step is skipped altogether, usually to not more than a few hundred milliliters (1 liter = 1000 milliliters [ml]), which is a volume of fluid that is significantly less than achieved using the *System 83 Plus*.

reprocessing systems may, for example, use a "boot," which may cause fluid invasion by damaging the endoscope's control head, seals, and gaskets, or the "all-channel irrigator," which is bifurcated and may deliver inadequate flow of the LCS to the endoscope's channels of greatest resistance;

➲ Specific reprocessing connectors, fittings, and channel-tubing adapters manufactured and sold by Custom Ultrasonics, Inc. may be required for thorough automated reprocessing of the endoscope. Contact Custom Ultrasonics to ensure use of the proper connectors, fittings, and adapters for each endoscope model in inventory. *Use of an improper connector, fitting, or adapter can result in ineffective reprocessing.*

☑ is designed to be used with virtually every legally-marketed LCS intended for reprocessing flexible endoscopes (refer to: *http://www.fda.gov/cdrh/ode/germlab.html).*

➲ *Contact Custom Ultrasonics before replacing one type of LCS (or detergent) with another*;

☑ is computer-controlled and features a keyboard and video monitor for displaying its user-friendly graphic interface. This keyboard can be used with a cover;

☑ features a computer-controlled timer that ensures the endoscope is immersed in the detergent and LCS for the recommended or indicated time. ➲ *Failure to immerse the endoscope in the detergent and LCS for the recommended time (and temperature) and at the appropriate concentration may result in ineffective reprocessing;*

☑ features a printer and software database that record each cycle's reprocessing parameters, such as the LCS's immersion time and temperature; the physician's name; the patient's name; the endoscope's manufacturer, model and identification (or serial) number; the date; and the duration of each reprocessing cycle. It is recommended that these reprocessing parameters be recorded, printed-out, and archived for future reference. ➲ *Failure to do so could hinder an investigation of the source and cause of an infection or outbreak*;

☑ features a third water rinse that follows high-level disinfection. Three water rinses are typically required, per the LCS's labeling. The *System 83 Plus* is designed to ensure the proper fluid level for complete immersion of the endoscope. ➲ *Failure to rinse the endoscope with fresh water for the proper number of times, at the recommended volume, and for the recommended time may result in ineffective reprocessing;*

☑ features "high-pressure" outputs designed to irrigate the endoscope's narrower and harder-to-reprocess accessory channels—such as, the colonoscope's auxiliary water jet channel and the side-viewing duodenoscope's elevator-wire channel. Standard pressure outputs designed to irrigate the endoscope's suction and air/water channels;

➲ *Visual confirmation of fluid flow into each endoscope channel, including the ERCP duodenoscope's elevator-wire channel, via each channel-tubing adapter is necessary, to ensure effective reprocessing. Failure to achieve adequate flow through each of the endoscope's channels during automated processing may result in ineffective reprocessing.*

3 Provided the difficult-to-reprocess accessory channels (i.e., the elevator-wire channel, the auxiliary water jet channel) have been properly pre-cleaned and determined not to be obstructed, occluded, or damaged, these channels can be reprocessed using the *System 83 Plus*.

Alternatively, these channels can be manually reprocessed in accordance with the specific endoscope model's reprocessing instructions, followed in sequence by reprocessing the entire endoscope, including its exterior, valves, and other channels and surfaces using the *System 83 Plus*, with the accessory channel connected to the *System 83 Plus* via the proper channel-tubing adapter.

☑ features stainless steel internal components, to ensure compatibility with most oxidizing (and aldehyde-based) LCSs;

☑ is used in conjunction with a water filtration assembly. This assembly typically includes a 5 micron sediment pre-filter and 0.1 micron bacterial post-filter. This assembly may also include a 25 micron pre-filter, depending on the quality of the facility's water;

3 *Use of the water filtration assembly supplied by Custom Ultrasonics, Inc. is recommended to produce as required bacteria-free rinse water. Contact Custom Ultrasonics, Inc. before purchasing a bacterial filter from another manufacturer or vendor.* Most bacterial filters are not labeled specifically for producing water intended for rinsing medical instruments or for use with hemodialyzers, but may instead be less effective and may not produce bacteria-free rinse water, posing a safety risk. Only the use of a bacterial filter that is labeled for the specific application of reprocessing endoscopes (or hemodialyzers) is recommended. ➲ *Use of improper water filters may result in contaminated rinse water, instrument re-contamination, ineffective reprocessing and adverse consequences.*

Moreover, proper replacement and insertion of the pre– and post–filters, as well as proper maintenance and decontamination of the water filtration assembly's housing (and the *System 83 Plus*), are important to patient safety and the production of bacteria-free rinse water. (Refer to the *System 83 Plus's* operator's manual.)

3 Potable tap water is an installation requirement for using the System 83 Plus and its water filtration assembly. Use of the *System 83 Plus* is contraindicated whenever the quality of the facility's potable tap water becomes compromised and requires boiling before drinking due to, for example, a natural disaster, such as a hurricane or flooding. Use of the *System 83 Plus* for reprocessing endoscopes may resume once water drinking restrictions have been removed. ➲ *Contact Custom Ultrasonics, Inc. for more information in the event of a boil-water alert.*

Note that changing of the water filter and decontamination of the water filtration assembly's housing and some of the internal components of the *System 83 Plus* (refer to the operator's manual) may be necessary before placing the *System 83 Plus* back on-line after the issuance of a boil-water alert (see: *http://www.bt.cdc.gov/disasters/watersystemrepair.asp* as well as *http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5210a1.htm*).

☑ is designed to facilitate manually rinsing each of the endoscope's internal channels with 70% isopropyl alcohol, to facilitate drying after completion of each reprocessing cycle;

☑ features an air compressor that removes most of the rinse water from the endoscope's channels after each reprocessing phase. Manual activation of this air compressor for extended drying after completion of the reprocessing cycle may be necessary, depending on the endoscope model. This air compressor is designed to be used in conjunction with a 70% isopropyl alcohol rinse. Additional compressed air drying may be necessary before storage of the endoscope to thoroughly dry endoscopes with long internal channels;

➲ *Air bubbles produced by this air compressor immediately following rinsing the endoscope's channels with 70% isopropyl alcohol can be used to visually confirm flow through each channel-tubing adapter, as required for effective reprocessing of each endoscope channel.*

3 Although the *System 83 Plus* is a stand-alone reprocessor that both washes and high-level disinfects immersible flexible endoscopes, it may be used in conjunction with: (**1**) a **pre-processing sink** that flushes each of the endoscope's channels with detergent during manual pre-cleaning; and (**2**) a **drying cabinet** that provides proper ventilation and a dry environment by purging each of the endoscope's channels with forced air during storage, which is important to the prevention of bacterial colonization. *Contact Custom Ultrasonics for more information about these two accessories.*

☑ high-level disinfects its internal components and most of its plumbing lines during routine endoscope reprocessing. Periodically scheduled overnight-disinfection/sterilization of some internal components and some plumbing lines is still required. *Refer to the System 83 Plus's service manual or contact Custom Ultrasonics, Inc. for more information*.

4. Process Monitors:

The System 83 Plus *Washer-Disinfector* features several different components that monitor its automated process, including:

☑ a heater that elevates the temperature of the LCS, as may be necessary. During reprocessing, the temperature of the LCS is monitored and controlled as it circulates in the processing basin and flows through the endoscope's internal channels. ➲ *Failure to irrigate the endoscope's channels with the LCS at the recommended temperature may result in ineffective reprocessing and adverse consequences;* and

☑ a pressure sensor to ensure that the re-circulating fluid pump is operating properly.

5. Summary: *Clinical in-use data*

Clinical in-use data collected from several health care facilities demonstrated that the *System 83 Plus* in the clinical setting effectively cleans and high-level disinfects the endoscope.

6. Summary: *Simulated in-use data collected under worst-case conditions using a patented decontamination protocol*

Background: A unique and patented, simulated in-use protocol (U.S. Patent No. 6,428,746) was used to evaluate and validate the effectiveness of the *System 83 Plus*.

Materials and Methods: All pre-market simulated in-use tests were performed using this patented protocol under *worst-case* conditions as required to pose a more formidable challenge than encountered clinically, thereby building into the data a margin of safety for the patient. To satisfy this requirement, tests were performed using a side-viewing ERCP (Pentax) duodenoscope (see *Section 7*, below, for data collected using an Olympus ERCP duodenoscope), which arguably is the most complex type of endoscope to reprocess, due in part to its long and narrow elevator-wire channel.

➲ As previously stated, demonstration that the *System 83 Plus* can effectively clean and high-level disinfect a duodenoscope reasonably indicates that virtually all types of endoscopes less complex in design can also be successfully reprocessed using the *System 83 Plus*, provided all of the endoscope's potentially contaminated surfaces are accounted for, adapted to, and in contact with the detergent, high-level disinfectant, and rinse water (see *Section 7*, below).

No manual pre-cleaning steps were performed on the endoscope or its valves prior to evaluating and validating the effectiveness of the *System 83 Plus*. This omission is required and is an integral component of worst-case-condition testing. Tergal 800, an alkaline detergent specifically intended for ultrasonic cleaning, and a solution of alkaline glutaraldehyde were used to evaluate and validate the effectiveness of the *System 83 Plus*.

A chromatographic device capable of detecting residues of glutaraldehyde was used to evaluate the effectiveness of the *System 83 Plus's* water rinses that follow chemical immersion. (During testing, two water rinses followed high-level disinfection.) A water filtration assembly that includes a 0.1 micron 510(k)-cleared bacterial filter was connected to the *System 83 Plus* to produce bacteria-free rinse water during testing.

A. *Glutaraldehyde:* Cidex (14-day alkaline glutaraldehyde solution) was used during testing of the *System 83 Plus*. Testing using another high-level disinfectant/sterilant (LCS) is unnecessary, because similar reductions in bioburden and microorganisms would be expected, provided the LCS is specified for high-level disinfecting flexible endoscopes and is used in accordance with its labeling claims, published guidelines, and the medical literature.

B. *Positive control, test instruments:* "Positive controls" were used during simulated in-use testing, to ensure that the measured log reductions were not due to artifact or chance, but to the effectiveness of the *System 83 Plus.* Positive controls are endoscopes that are artificially inoculated with microorganisms but that are *not* exposed to the cleaning or high-level disinfection and, therefore, remain contaminated.

Positive controls confirm successful contamination of each of the endoscope's surfaces and are used to determine the number of microorganisms that can be removed and recovered from each of the endoscope's contaminated surfaces using specific and prescribed sampling techniques, as required to calculate a log reduction.

Test endoscopes are also artificially inoculated with microorganisms, but, unlike positive controls, these endoscopes *are* exposed to cleaning and high-level disinfection. Comparison of the number of microorganisms remaining on each of the *test* endoscope's surfaces to the number of microorganisms recovered from each of the respective positive control's (contaminated) surfaces permits calculation of an average log reduction for *each* surface. In general, the greater the log reduction, the more effective the decontamination process.

To account for statistical variance, data from 3 *test* endoscopes (i.e., 3 test replicates) were collected to calculate an average log reduction (n=3) achieved by the *System 83 Plus* for each contaminated surface. The average log reduction achieved during the wash phase was determined by comparing for each endoscope surface the number of microorganisms, measured in CFUs or colony forming units, recovered from the "positive control" endoscope's surfaces to the average (n=3) number of microorganisms (also measured in CFUs) recovered from each respective washed surface of the three *test* endoscopes (Table 2). The same principle was used to determine the average log reduction achieved during high-level disinfection.

C. ***Mycobacteria:*** Because of their clinical significance and high resistance to liquid chemical sterilants/disinfectants (LCSs), resistant mycobacteria (in lieu of bacterial endospores) are used during simulated in-use testing to evaluate high-level disinfection effectiveness. These same organisms were also used as markers to evaluate cleaning effectiveness. All tests were performed by an independent laboratory in accordance with *Good Laboratory Practices*.

D. ***Washing:*** The effectiveness of the wash phase of the *System 83 Plus* was evaluated under *worst-case* conditions by inoculating several endoscope surfaces—specifically, each of the side-viewing duodenoscope's **internal channels,** the **biopsy port, air/water valve cylinder** and **suction valve cylinder,** the exterior of the **insertion tube**, and the **suction valve** and **air/water valve**—with approximately *one hundred million* colony forming units per milliliter (or, 10^8 CFUs/mL) of *Mycobacterium terrae*, an organism similar in its resistance to LCSs as the causative agent of tuberculosis. These resistant microorganisms were mixed with an organic soil that included bovine serum, to simulate contaminated patient debris (i.e., bioburden).

3 The tests performed to evaluate washing effectiveness were performed using **Tergal 800,** an ultrasonic (alkaline) detergent. *Contact Custom Ultrasonics, Inc. before using another type of detergent. Use of an un-tested detergent is not recommended and may affect cleaning effectiveness. Independent data substantiating the advertised claims of most enzymatic detergents have not been published.* *See page 3 for more information about acceptable detergents.*

E. ***High-level disinfection:*** Similarly, the effectiveness of the high-level disinfection phase of the *System 83 Plus* was evaluated under *worst-case* testing conditions. Each of several surfaces of a duodenoscope were inoculated with 10^8 CFUs/mL of *Mycobacterium terrae* as described, above, for evaluating the *System 83 Plus's* wash phase. Glutaraldehyde (Cidex) was used during testing. Water and more than a liter of calf's blood serum were added to this solution of glutaraldehyde, to simulate worst-case reuse conditions, and to reduce the disinfectant's concentration (as usually occurs during high use or near the disinfectant's expiration date).

F. ***Water rinse:*** The effectiveness of the *System 83 Plus's* **water rinse phases** that follow in sequence the high-level disinfection phase was evaluated using an immersion technique, to

determine whether these water rinses reduced to safe levels any glutaraldehyde that might have remained on the endoscope's surfaces after high-level disinfection. (Two water rinses instead of three were used during testing.)

G. ***Criteria of acceptability:*** The criterion of acceptability of a cleaning process requires demonstration of at least a 99.9% (or 3 log) reduction of the initial amount of contamination each of the endoscope's surfaces. The *System 83 Plus's* wash phase, therefore, would be deemed successful and the criterion of acceptability for cleaning would be satisfied if it achieved, for *each* inoculated site per the patent's requirements, an average log reduction of resistant mycobacteria of at least 3.

Similarly, the criterion of acceptability of a high-level disinfection process requires demonstration of at least a 6 log reduction of initial amount of contamination each of the endoscope's surfaces. The *System 83 Plus's* high-level disinfection phase, therefore, would be deemed successful and the criterion of acceptability for high-level disinfection would be satisfied if it achieved, for *each* inoculated site per the patent's requirements, an average log reduction of resistant mycobacteria of at least 6.

And, the criterion of acceptability of a water-rinsing process requires that only a safe level of glutaraldehyde be detected on the endoscope's surfaces after completion of the water-rinse phase that follows high-level disinfection.

H. ***Sampling, microorganism recovery****:* The final number of viable mycobacteria (if any) remaining on each of the several aforementioned endoscope surfaces after exposure to the *System 83 Plus's* wash phase and, performed separately, its high-level disinfection phase was determined by aseptically flushing with sterile water the endoscope's internal channels, biopsy port, and air/water and suction valve cylinders and separately (and aseptically) collecting the effluent from each surface. Each endoscope channel was flushed with a volume of sterile water equal to three times the channel's void volume. (For comparison, the endoscope's accessible surfaces were also sampled using a sterile brush. These data are not included in the Tables 2, 3, and 4, below.) The collected effluent for each surface was cultured separately, and the number of viable mycobacteria was counted for each endoscope surface, to determine the log reduction achieved by the *System 83 Plus* for *each* endoscope surface. For both the cleaning phase and the high-level disinfection phase, this sampling procedure was repeated 3 times, allowing for the calculation of an average log reduction for each endoscope surface.

Results: The results of the **wash** phase of the *System 83 Plus* are displayed in **Table 2.** The data show that the *System 83 Plus* satisfies this test's criterion of acceptability (achieving an average log reduction of at least 3 on each of the endoscope's surfaces). These data also show that the average log reduction achieved on each surface is comparable to (i.e., not inferior to) the published log reduction achieved during manual cleaning. Unlike manual cleaning, however, which is inherently variable, the *System 83 Plus's* wash phase is automated, standardized, and validated.

A similar set of calculations was performed to evaluate the effectiveness of the *System 83 Plus's* **high-level disinfection** phase (no manual pre-cleaning or automated washing). These results, which are displayed in **Table 3,** show that the *System 83 Plus* satisfies this test's criterion of acceptability (achieving an average log reduction of at least 6 on each of the

Endoscope surface, site	Number of CFUs recovered from the positive control's surface	Average number (in CFUs) recovered from the washed surface	Average log_{10} reduction
Channels, biopsy port, valve cylinders	1.5×10^9	5.6×10^5	**3.4**
Insertion tube	6.1×10^7	2.3×10^3	**4.6**
Suction valve, air/water valve	3.2×10^6	2.4×10^3	**4.0**

Table 2: *The **cleaning** data during simulated in-use testing.* These data (column 4) indicate that the criterion of acceptability of a cleaning process (a 3 or more log reduction) is satisfied. *CFUs* in Table 2 refer to *colony forming units*.

endoscope's surfaces), save for the endoscope's suction and air/water valves (Table 3). (Refer to Table 3 and its associated footnote.)

If no precleaning is performed, the System 83 Plus *Washer-Disinfector* can be expected to achieve a final log reduction of approximately **9 logs** in the endoscope's channels—the sum of the average log reductions achieved separately for automated **washing** (**3-4 logs**, **Table 2**) and for automated **high-level disinfection** (**6 logs**; **Table 3**), because the *System 83 Plus's* wash and high-level disinfection phases are separate standardized phases that operate in sequence, one after the other. These data are displayed in **Table 4**.

No residues of glutaraldehyde were detected on the endoscope after the *System 83 Plus's* terminal water rinses (data not displayed), satisfying the rinse water test's criterion of acceptability. Also, no microorganisms or bacterial biofilms were detected in any of the *System 83 Plus's* internal components (e.g., plumbing lines, solenoids) during worst-case testing.

Discussion: **Tables 2, 3** and **4** demonstrate that the *System 83 Plus*: (**1**) automates and standardizes the wash, high-level disinfection, and water rinse phases; (**2**) achieves a log reduction during automated washing equivalent to (i.e., not inferior to) manual cleaning; (**3**) achieves (at least) a 6 log reduction of mycobacteria during high-level disinfection under *worst-case* conditions; and (**4**) may permit the safe use of 2% glutaraldehyde at an immersion time of 20 minutes (as opposed to 45 minutes) at room temperature to achieve high-level disinfection (refer to: Muscarella LF. Soaking endoscopes in 2% glutaraldehyde for 20 minutes. *Am J Infect Control* 1998 Apr;26(2):153-5).

All simulated in-use tests were performed using a patented decontamination protocol (U.S. Patent No. 6,428,746) that compares the number of microorganisms recovered from several different surfaces of positive controls (which, if the recovery efficiency is 100%, equals the number of microorganisms artificially inoculated onto the endoscope's multiple surfaces)—remember that positive controls are instruments that are *not* exposed to cleaning or high-level disinfection—to the number of microorganisms remaining on each of these respective surfaces *after* exposure of the *test* endoscopes to either cleaning or high-level disinfection, depending on

Endoscope surface, site	Number of CFUs recovered from the positive control's surface	Average number (in CFUs) recovered from the high-level disinfected surface	Average log_{10} reduction
Channels, biopsy port, valve cylinders	1.5×10^9	1.9×10^4	**6.0**
Insertion tube	6.1×10^7	6.9×10^2	**7.6**
Suction valve, air/water valve	2.9×10^7	3.5×10^3	**4.2**

Table 3: *The **high-level disinfection** data during simulated in-use testing.* These data (column 4) indicate that the criterion for acceptability of a high-level disinfection process (a 6 or more log reduction) is satisfied.[†] *CFUs* in Table 3 refer to *colony forming units*.

which is under evaluation. For the endoscope to be considered cleaned or high-level disinfected, this patented protocol requires that the necessary log reduction be achieved, not just for one of the instrument's several surfaces, but rather for *each* of the endoscope's several inoculated surfaces, including its exterior, both valves, and each internal channel.

In contrast to this patented protocol, ASTM's published simulated in-use decontamination standards for cleaning and disinfection (and sterilization) are based, not on the patient's *per site* paradigm, but rather on ASTM's *per instrument* paradigm, which does not require that the necessary log reduction be achieved on *all* of the endoscope's several surfaces. This *per instrument* paradigm is significantly less rigorous than the *per site* paradigm and can yield false-negative results that erroneously suggest that an unsuccessful process is effective.

For example, in contrast to the patent, ASTM's criterion of acceptability for high-level disinfection requires achieving an average log reduction of at least 6 on only one, as opposed to each, of the endoscope's surfaces. As a result, provided the required log reduction is achieved for just one of the instrument's several surfaces, ASTM's standards deem the decontamination process effective for the entire instrument, even though several of the instrument's other surfaces might be heavily contaminated after exposure to the decontamination process under evaluation. The distinction between this patented protocol and ASTM's decontamination standards is profound. ➲ *Use of a protocol that complies with the "per site" paradigm is essential to evaluate the effectiveness of a decontamination process, to ensure patient safety, and to avoid erroneous conclusions based on false-negative results.*

[†] During this set of simulated in-use tests, the concentration of glutaraldehyde was measured and determined to be less than 1.0%. This concentration is well below 1.5%, the minimum effective concentration (MEC) of glutaraldehyde that is recommended by the FDA. Use of glutaraldehyde at a concentration below 1.0% explains why during testing the average log reduction reported in Table 3 for the endoscope's valves was below 6. If these tests had been performed at a 50% higher glutaraldehyde concentration of 1.5%, then the data would have demonstrated a significantly higher log reduction of mycobacteria than 4.2 logs (i.e., greater than 6 logs), thereby satisfying the 6 log requirement for high-level disinfection. This conclusion was confirmed by subsequent testing (see "*Section 7*").

Endoscope surface	Total Average log_{10} reduction
Channels, biopsy port, valve cylinders	Wash: 3.4; High-level disinfection: 6.0 **Total = 9.4**
Insertion tube	Wash: 4.6; High-level disinfection: 7.6 **Total = 12.2**
Suction valve, air/water valve	Wash: 4.0; High-level disinfection: 4.2 **Total = 8.2**

Table 4: ***Combination*** *of the* ***cleaning*** *and* ***high-level disinfection*** *data.*

Remember that all of the simulated in-use tests performed during validation testing of the *System 83 Plus* (Tables 2, 3, and 4) used the patented simulated in-use protocol under *worst-case* conditions. A greater log reduction than displayed in these tables would, therefore, be expected in the clinical setting for a number of reasons including:

- manual pre-cleaning, which is reported to reduce the bioburden on the endoscope by approximately 3-4 logs (i.e., 99.9% to 99.99%) and is recommended by all endoscope reprocessing guidelines, was not performed prior to evaluation of the *System 83 Plus's* automated wash phase or high-level disinfection phase; and
- the solution of glutaraldehyde used during testing was at a concentration below 1.0% (refer to the footnote on the bottom of page 12). Ordinarily, the concentration of glutaraldehyde is monitored in the clinical setting and is 1.5% or higher.

Additionally, more favorable results would be expected when reprocessing endoscopes that are simpler in design—and, therefore, easier to clean and high-level disinfect—than the complex ERCP duodenoscope used during these simulated in-use tests (see *Section 7).*

A. ***Managing risk:*** The data displayed in Table 2 suggest that the automated cleaning provided by the *System 83 Plus* may reduce the risk of disease transmission in the event that a staff member was overburdened and failed to manually pre-clean all of the endoscope's contaminated surfaces as prescribed by published guidelines. *Cleaning is the first and most important step in any instrument processing protocol.* Without subjecting the instrument to a thorough cleaning process, the likelihood that any disinfection or sterilization process will be effective may be significantly reduced. (Note that the *System 83 Plus* is intended to complement, not replace, manual pre-cleaning.)

Moreover, provided the endoscope is manually pre-cleaned in accordance with published guidelines reducing the bioburden by approximately 3-4 logs, the *System 83 Plus's* compensational and standardized automated cleaning phase, which itself also reduces the bioburden on the endoscope by approximately 3-4 logs, would be expected to minimize the risk of disease transmission in the event that high-level disinfection was only marginally achieved,

as might occur when the disinfectant's concentration is not properly monitored and is found to be below its 'minimum effective concentration' (MEC) during routine use. (Refer to: *Muscarella LF. The risk of disease transmission associated with inadequate disinfection of gastrointestinal endoscopes. J Hosp Infect 2006 Jul;63(3):345-7.)*

B. ***Endoscope's air/water, suction valves:*** The simulated in-use patented protocol used to evaluate the effectiveness of the *System 83 Plus* requires the contamination of, among other endoscope surfaces and sites, the endoscope's **air/water valve** and **suction valve**.[†]

3 The labeling of some models of AERs or systems acknowledges their limitations and their inability to reprocess the endoscope's reusable suction valves and air/water valves, requiring instead that these valves be reprocessed manually, in accordance with the healthcare facility's policies and procedures. *Successful reprocessing of both of these valves (assuming they are not disposable) is essential to the evaluation of the effectiveness of any AER or system.* ➲ *Failure to reprocess both valves may result in ineffective reprocessing and disease transmission.*

C. ***Monitoring the rinse water:*** The *System 83 Plus* is designed to be used with a water filtration assembly that includes a 0.1 micron bacterial filter. But, while 0.1 or 0.2 micron bacterial filters improve the microbial quality of the rinse water, they are not fail-safe, and over time they can become worn and stressed and allow bacteria to leak across their membrane, resulting in re-contamination of the rinse water and the rinsed instrument. Only when new and under ideal conditions might a bacterial filter produce "bacteria-free" rinse water. Drying the endoscope after reprocessing is necessary, nevertheless, irrespective of whether the rinse water is filtered, because re-contamination of the rinsed instrument can result in an increased risk of disease transmission. ➲ *"Sterile" water cannot be produced in a healthcare setting by filtering tap water through a 0.2 micron bacterial filter. Among other requirements, the production of sterile water requires a sterile (e.g., class 100) environment, sterile plumbing, and steam sterilization prior to filtering the water across the 0.2 micron filter.*

Although rarely considered, it is arguably necessary to microbiologically monitor the rinse water's microbial content. *Indeed, the rinse water is the Achilles' heel of endoscope reprocessing, and the "quality" of an reprocessed instrument is limited by, and can only be as good as, the microbial quality of the water used to terminally rinse the instrument after chemical immersion, whether reprocessing the instrument manually or using an AER or liquid processing system. Contaminated rinse water yields contaminated instruments, irrespective of the potency and effectiveness of the liquid chemical sterilant/disinfectant.*

But, the rinse water used during endoscope reprocessing is not typically monitored microbiologically, and, therefore, its microbial quality and endotoxin content are rarely known, making the outcome of the rinsed instrument (e.g., high-level disinfected) also unknown. *Assurances that the endoscope was successfully high-level disinfected or "sterilized" cannot be made if the rinse water is not microbiologically monitored and its microbial quality unknown.*

[†] The simulated in-use testing protocols used by some manufacturers fail to evaluate how effectively their AER (or "system") can reprocess the endoscope's suction and air/water valves, even though both are integral components of the endoscope. Without the data to demonstrate that both of these valves can be successfully reprocessed, the effectiveness of the AER (or "system") would be in doubt. Indeed, the literature contains reports documenting nosocomial infections linked to inadequately reprocessing endoscope valves.

Moreover, routinely monitoring the rinse water used during endoscope reprocessing is important, among other considerations, to determine when the bacterial filter is beginning to fail and to allow bacteria to pass, resulting in re-contamination of the endoscope and the need for its prompt replacement. Relying solely on a pre-determined pressure gradient across the bacterial filter's membrane (e.g., 25 PSI)—or an automated visual or audible or diagnostic alarm—as the gauge for determining whether the bacterial filter requires replacement is inadequate. Without microbiologically monitoring the rinse water and its microbial content, the outcome of the instrument and the validity of the AER's (or system's) label claims to disinfect or "sterilize" an instrument is in doubt. (► For a detailed discussion of monitoring the rinse water, refer to: Muscarella LF. Application of environmental sampling to flexible endoscope reprocessing: the importance of monitoring the rinse water. *Infect Control Hosp Epidemiol* 2002 May;23:285-9.)

Conclusion: A unique simulated in-use patented (U.S. Patent No. 6,428,746) protocol was used to evaluate the effectiveness of the *System 83 Plus*. Data acquired during testing using this protocol (as well as during clinical in-use testing and process-parameter testing) validate the System 83 Plus *Washer-Disinfector* for the effective washing, high-level disinfecting, and water rinsing of one or two flexible endoscopes at a time.

7. Additional Post-Market Data: The cleaning and high-level disinfection of: ● *bronchoscopes* ● *double channel colonoscopes* ● *ERCP duodenoscopes,* ● *GI endoscope suction and air/water valves* ● *hysteroscopes* ● *cystoscopes*

A. ***Introduction:*** Custom Ultrasonics often receives requests from healthcare facilities asking whether the *System 83 Plus* effectively reprocesses flexible endoscopes other than the Pentax ERCP duodenoscope used during simulated in-use testing described above, such as Olympus ERCP side-viewing duodenoscopes, double channel colonoscopes with an auxiliary water jet, laryngoscopes, hysteroscopes, and cystoscopes, as well as the suction and air/water valves of different models of gastrointestinal (GI) endoscopes (and of bronchoscopes).

These requests appear to be a result of discussions, correspondence, and published manuals that indicate that several AERs or liquid process systems marketed in the U.S. are contraindicated for reprocessing some of these types of endoscopes and their valves. As a result, the operator's manuals of these AERs (or systems) instruct users to manually reprocess these endoscopes and their valves in accordance with either the healthcare facility's own policies and procedures or the endoscope manufacturer's instructions.

Such labeling indicates that data showing that every AER (or system) on the market can reprocess these types of endoscopes and their valves are lacking. *Failure to publish data demonstrating the effectiveness of an AER (or system) for reprocessing an endoscope's valves would call into question the effectiveness and labeling of the AER (or system).*

B. ***Olympus 140 series ERCP duodenoscopes:*** In response to requests from healthcare facilities to complement the studies previously performed using a Pentax ERCP duodenoscope (Tables, 2, 3 and 4, above), Custom Ultrasonics in the winter of 2001 performed a series of additional simulated in-use tests using a patented protocol (U.S. Patent No. 6,428,746) under *worst-case* conditions. During these tests, an Olympus 140 series ERCP duodenoscope (model type: JF140) was used, to evaluate the effectiveness of the *System 83 Plus*. A high-pressure

pump was used to irrigate the endoscope's elevator-wire channel. For variation, Sporox® II, a hydrogen peroxide-based liquid sterilant/disinfectant, was used instead of glutaraldehyde. This sterilant was reduced to its minimum effective concentration (MEC) of 6.0%. The endoscope was neither manually pre-cleaned nor automatically cleaned using the *System 83 Plus's* ultrasonic wash phase prior to high-level disinfection. Simulated in-use testing was performed using a chemical immersion time and temperature of 15 minutes (at 25° C), the label's 30 minute label claim at room temperature notwithstanding. Data from 5 test replicates (instead of the usual 3) were collected.

The results demonstrate that the *System 83 Plus* successfully high-level disinfects not only all of the endoscope's internal channels, including **the elevator-wire channel**, but also the endoscope's **suction** and **air/water valves**. (Again, these results were obtained without any manual or automated cleaning.) Because manual pre-cleaning is the standard of care and shown to reduce the level of bioburden by approximately 3-4 logs, a significantly greater log reduction would be expected if, in addition to high-level disinfection, the endoscope were manually pre-cleaned and cleaned using the *System 83 Plus's* automated wash phase.

➲ *If there is any concern or doubt that: (**a**)* the System 83 Plus *has properly reprocessed the endoscope and its suction channel, and/or (**b**)* the System 83 Plus *has been properly maintained or is operating properly, then it is recommended that the endoscope be* manually *reprocessed in accordance with SGNA's guidelines and the instructions provided by the endoscope manufacturer.*

C. *Olympus 160 series colonoscopes:* Custom Ultrasonics in the spring of 2002 performed more tests under *worst-case conditions* (e.g., no manual pre-cleaning) using a simulated, in-use patented (U.S. Patent No. 6,428,746) protocol to evaluate the effectiveness of the *System 83 Plus* for reprocessing the Olympus 160 series colonoscope (model type: CF-Q160L). In addition to other surfaces, attention during this test focused on the effectiveness of the *System 83 Plus* on the suction valve and air/water valve and inside the auxiliary water jet channel. A high-pressure pump was used to irrigate the auxiliary water jet channel. These tests were performed using Tergal 800 during a 3 minute automated wash phase and glutaraldehyde at a concentration of 1.5% during a 20 minute automated high-level disinfection phase at 25° C.

The results of these tests demonstrate that during its automated wash phase the *System 83 Plus* reduces the number of microorganisms on the colonoscope's suction valve, air/water valve, and auxiliary water jet channel by more than 3 logs (i.e., 99.9%). Completion of the *System 83 Plus's* entire cycle, which also includes high-level disinfection, resulted in more than a 6 log reduction of resistant microorganisms for each of these surfaces.

► These data suggest that a 20 minute immersion time for glutaraldehyde may be adequate to prevent disease transmission provided the endoscope is first subjected to a standardized and automated cleaning phase**.** (Refer to: Rutala WA, Weber DJ. *Infect Control Hosp Epidemiol* 1995 Apr;16(4):231-5.)

D. *Bronchoscopes:* Custom Ultrasonics, Inc. in the summer of 2003 performed more tests under *worst-case* conditions (e.g., no manual pre-cleaning) using a simulated, in-use patented (U.S. Patent No. 6,428,746) protocol to evaluate the effectiveness of the *System 83 Plus* for

reprocessing bronchoscopes. A Pentax bronchoscope (model type: EB-1970K) and Pentax colonoscope (model type: EC-3870LK) were simultaneously reprocessed, to assess the effectiveness of the *System 83 Plus* when reprocessing two endoscopes at a time. A high-pressure output were used to irrigate the colonoscope's forward water jet channel. The endoscopes' other channels were reprocessed using the *System 83 Plus's* standard pressure outputs. These tests were performed using Tergal 800 during a 3 minute automated ultrasonic wash phase and glutaraldehyde at its minimum effective concentration (or, MEC) of 1.5% during a 45 minute automated chemical immersion phase at 25° C.

The results of these tests indicate that the *System 83 Plus* successfully reprocesses the bronchoscope, including its suction channel, reusable suction valve, and biopsy port. Because the simultaneous reprocessing of a bronchoscope along with a colonoscope, which is a significantly more complex endoscope than a bronchoscope, did not adversely affect the log reduction achieved for any of the bronchoscope's surfaces, these results suggest that two bronchoscopes can be reprocessed at the same time using the *System 83 Plus*.

E. ***Double-channel colonoscopes, ENT endoscopes,*** *and* ***hysteroscopes****:* Custom Ultrasonics in July, October, and December of 2004 performed a series of simulated in-use tests using its patented (U.S. Patent No. 6,428,746) protocol to evaluate the effectiveness of the *System 83 Plus* for reprocessing a Pentax **double-channel colonoscope** (model type: EC-3870TLK; [70 series]), a Pentax **ENT endoscope** (naso-pharyngo-laryngoscope**)** (model type: FNL-10AP; single channel), and an Olympus **hysteroscope** (model type: HYF XP1). None of the endoscopes were manually pre-cleaned prior to automated reprocessing.

In addition to other surfaces, attention during these tests focused on the most difficult surfaces to reprocess, including: (a) the double-channel colonoscope's air/water channels, forward water jet channel, suction valve, air/water valve, suction valve housing, air/water valve housing, biopsy caps, and check valve; (b) the ENT endoscope's working channel; and (c) the hysteroscope's working channel. To complement the results of previous tests, the effectiveness of the *System 83 Plus* was evaluated for reprocessing the suction valve and air/water valve of an **Olympus 160 series** GI endoscope. No more than two of these endoscopes were reprocessed at one time in the *System 83 Plus's* processing chamber during this series of tests.

The *System 83 Plus's* high-pressure pump was used to irrigate the double-channel colonoscope's forward water jet channel (1.15 mm), the ENT endoscope's working channel (1.2 mm), and the hysteroscope's working channel (1.15 mm). The endoscopes' other channels were reprocessed using the *System 83 Plus's* standard pressure outputs. These tests were performed using Tergal 800 during a 3 minute automated wash phase and glutaraldehyde at a co concentration of 2.0% during a 45 minute automated chemical immersion phase at 25° C.

Additionally, both the Pentax and Olympus GI endoscopes' suction and air/water valves were reprocessed using a valve *block* adapter. Also, a cylindrical *turbo-tube* adapter was used to reprocess the endoscopes' biopsy port caps, check valves, and other endoscopic components. A modified door clamp adapter, manufactured specifically for attaching to and covering the suction and air/water valve housings of GI endoscopes, was used during these tests. This adapter's rubber fixture was designed to allow the reprocessing fluids to leak out from inside the GI endoscope, to ensure complete contact of the reprocessing fluids with the internal walls of these two valve housings during automated reprocessing.

The results of these tests indicate that the *System 83 Plus* successfully high-level disinfects (i.e., achieves more than a 6 log reduction of mycobacteria) the Pentax 70 series double-channel colonoscope's air/water channels and forward water jet channel (as well as its suction channel and exterior surfaces); the ENT endoscope's working channel; and the hysteroscope's working channel. The suction and air/water valves of both the Pentax colonoscope and the Olympus 160 series GI endoscope were successfully reprocessed using the block adapter. The double-channel colonoscope's suction valve housing and air/water valve housing were successfully reprocessed using the modified door clamp adapter. This endoscope's two biopsy caps and check valve were successfully reprocessed using the turbo-tube adapter.

F. ***An important paradigm for testing endoscopes:*** As displayed throughout this booklet, Custom Ultrasonics has published data that show the effectiveness of the *System 83 Plus* for reprocessing a number of different types of endoscope models, endoscope valves, and other types of detachable endoscopic components. Custom Ultrasonics believes these data are unrivaled. Provided, among other considerations, the correct channel-tubing adapters are used during reprocessing to connect the flexible endoscope properly to the *System 83 Plus*, and fluid flow through each channel has been confirmed, these published data can be used to reasonably conclude that the *System 83 Plus* can effectively reprocess endoscopes that are less complex—that is, feature internal channels that are shorter in length and wider in diameter and, therefore, pose less impedance to flow and are less formidable to reprocess—than an ERCP duodenoscope or a double-channel colonoscope, two types of endoscopes that the *System 83 Plus* has been shown to effectively reprocess. The same rationale can be reasonably applied to the suction valve and air/water valve of a new endoscope model. (New endoscope channel or valve designs may warrant additional testing before any reprocessing conclusions can be drawn.)

Although nothing replaces the collection and publication of simulated in-use data, review of the specifications and dimensions of a new type, model, or series of flexible endoscope may provide the number, length, and diameter of the endoscope's internal channels. Comparison of these specifications and dimensions to those of the channels of endoscopes for which Custom Ultrasonics has on file and has published simulated in-use data typically provides sufficient information to draw reasonable and appropriate conclusions about the effectiveness of the *System 83 Plus* for both cleaning and high-level disinfecting the endoscope type, model, or series in question. (Discussions between Custom Ultrasonics and the endoscope manufacturer may be necessary, to ensure proper adaptation and connection of the endoscope to the *System 83 Plus* as required for adequate reprocessing.)

By way of an example, the length and inner diameter of the working channel of the Olympus **cystoscope** (model CYF-4 [no suction valve or air/water valve]) is 380 mm and 2.4 mm, respectively. Comparison of these dimensions to, for example, the length and inner diameter of the forward water jet channel of the Pentax double-channel colonoscope (EC-3870TLK), a channel that: **(1)** Custom Ultrasonics, Inc. has tested and published data demonstrating the reprocessing effectiveness of the *System 83 Plus* (see above), and, **(2)** is significantly longer than 380 mm in length and considerably narrower in inner diameter than 2.4 mm, respectively, and, therefore, is more formidable to reprocess, yields the reasonable conclusion that the *System 83 Plus* can both clean and high-level disinfect the wider and shorter working channel of a flexible cystoscope. (Data on file show that the *System 83 Plus* both cleans and high-level disinfects the auxiliary water jet channel of the Olympus 160 series [CF-Q160L] colonoscope.)

Instead of simulated in-use data, other manufacturers may have on file measurements of the *pressures* and *flows* through the internal channels of different flexible endoscope types, models, and series. (Or, alternatively, these manufacturers may have on file microbiological data collected using ASTM's decontamination standards, which are prone to false-negative results). Pressure-flow data alone are inadequate and prevent drawing valid conclusions about the effectiveness of an AER (or system) for reprocessing flexible endoscopes. *For example, pressure-flow data cannot be used to draw conclusions about the effectiveness of an AER (or system) for reprocessing an endoscope's air/water valve or suction valve, which are both integral components of a GI endoscope.*

Custom Ultrasonics, Inc. is always updating its files and publishing new data using its patented simulated in-use decontamination protocol that validate the effectiveness of the System 83 Plus *Washer-Disinfector* for reprocessing newly introduced types, models, and series of flexible endoscopes, including their complex valves. The list of endoscopes for which Custom Ultrasonics, Inc. has published efficacy data grows each year.

8. Installation requirements[†]

WATER SUPPLY: Requires dedicated 1/2" hot and cold water supply lines with shut-off valves and 3/4" male garden hose adapters
Recommended water pressure: 40 - 50 PSI (with a water flow of approximately 8-10 gallons/minute)
Required water temperature: 105° F - 115° F
Required water quality: potable tap water

WASTE DRAIN: Requires for each reprocessing chamber a 2" diameter standpipe that is 18" above floor level (some models of the *System 83 Plus*™ may have more than one reprocessing chamber)

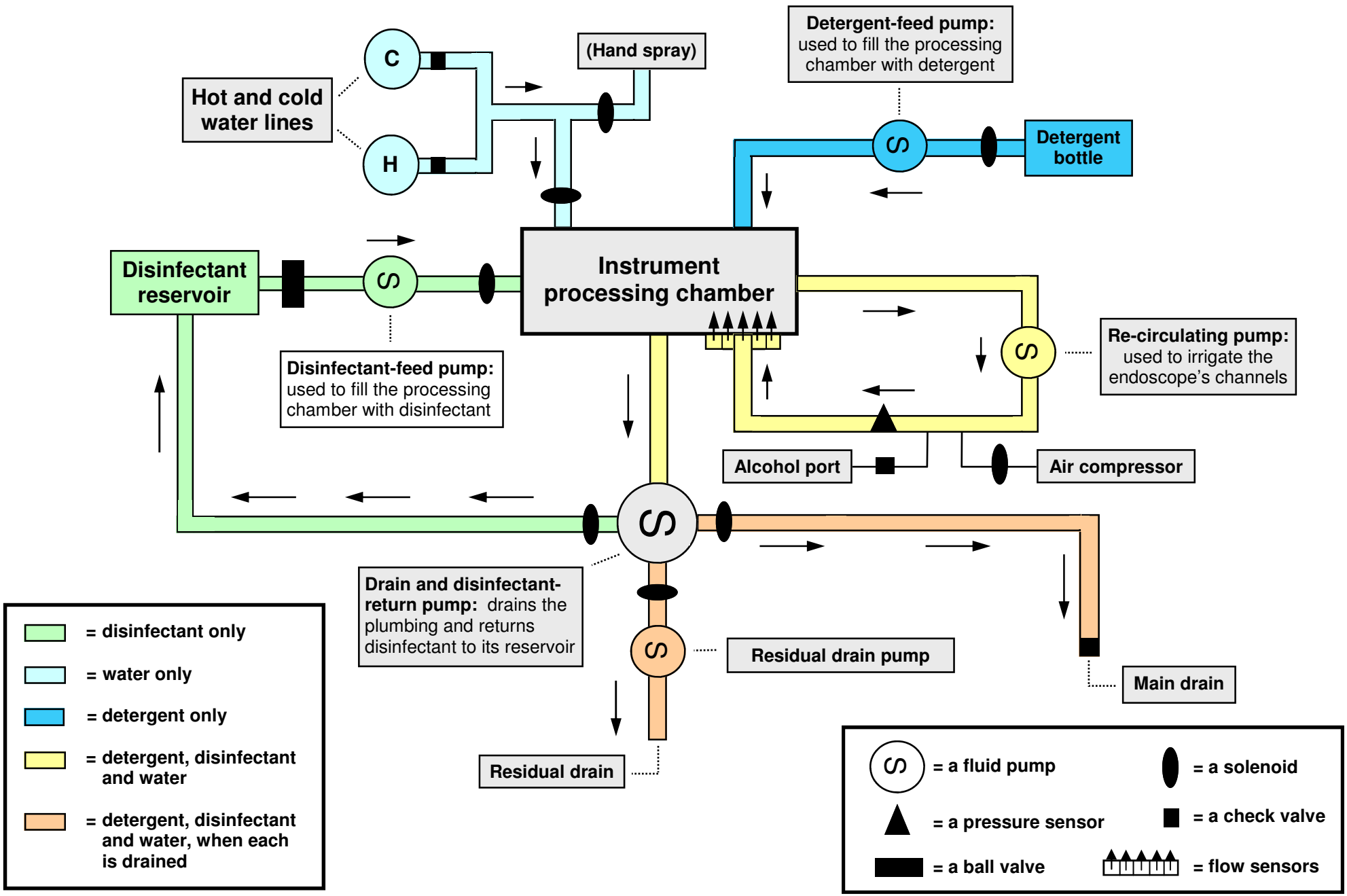
WATER FILTRATION: Filtered water is used during rinsing. The water filtration assembly is steam-autoclavable and includes a sediment filter (pre-filter; 5.0 micron) in-line with a 510(k)-cleared bacterial filter (post-filter; 0.1 micron) for both hot and cold water lines.

ELECTRICAL: A dedicated electrical receptacle: 110 volts, 20 amp, 60 Hz for each reprocessing chamber

* * * * *

[†] Certain variations to these requirements may be required and acceptable.

The System 83 Plus: General plumbing diagram of fluid flow during *all* automated reprocessing phases



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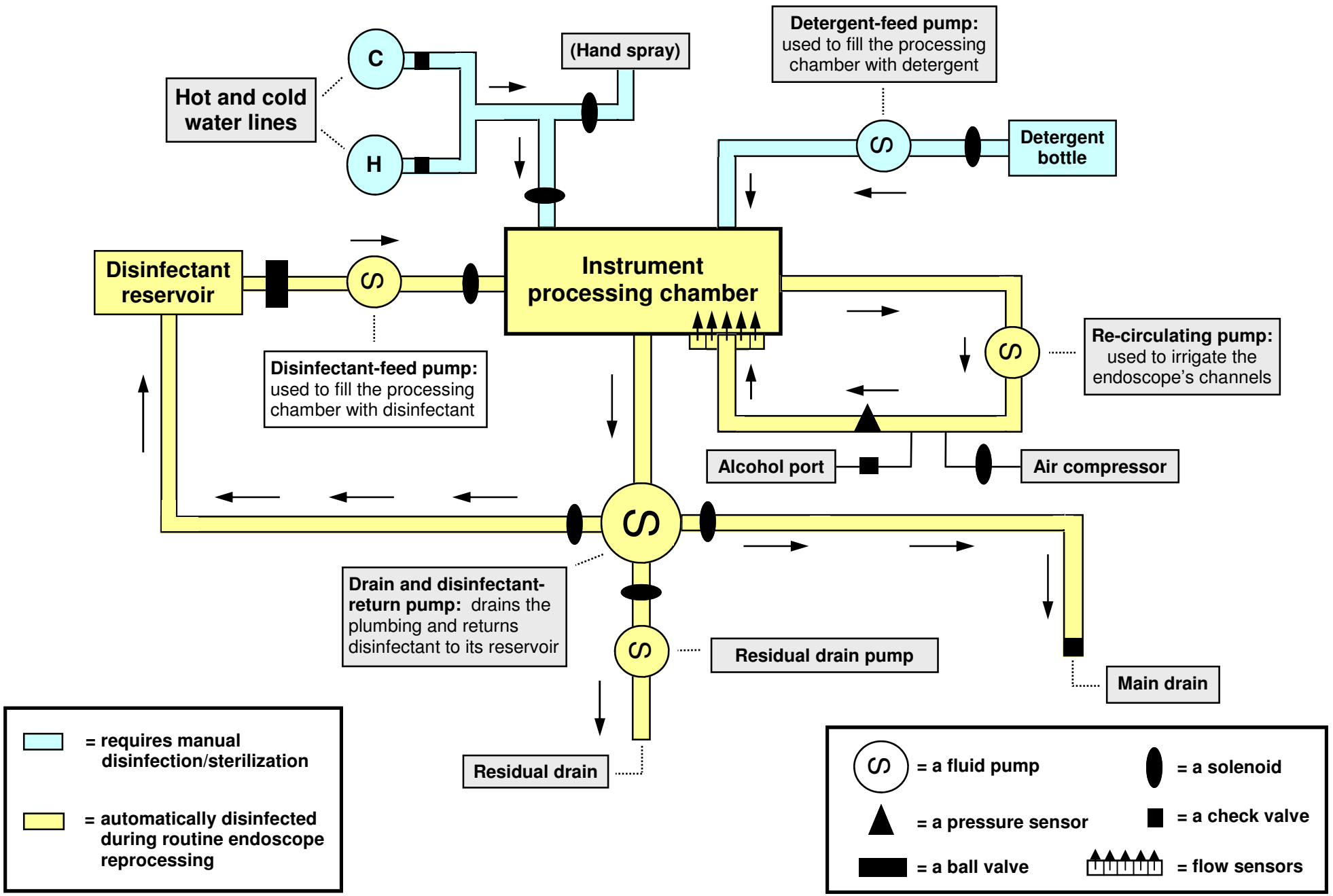
The System 83 Plus: Automatic and manual disinfection/sterilization of components



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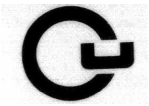

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